

510k Premarket Notification Summary

Date: July 13, 2010

Submitted by:

Sun Nuclear Corporation
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Melbourne, FL 32940
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Attn: Noel Downey

1K101992
OCT 1 2010

Classification Name: Accelerator, Linear, Medical

Common Name: Water Phantom Ionizing Radiation Dosimetry Scanner

Proprietary Name: 3D Scanner

Establishment Registration Number: 1038814

Classification: Class II, Classification IYE

Performance Standards: To our knowledge, none have been established

Substantial Equivalence: This instrument is similar in function to IBA RFA- 200. SNC was not able to specifically identify the RFA-200 510k identification number in the FDA database, it may be a subset of the RFA-300 510k (Scanditronix RFA A-300), K934303. This is substantiated by references to RFA-200 in RFA-300 documentation.

Description and Use:

The 3D Scanner Model 1230 is an electromechanical and software system that includes:

1. a cylindrical tank to contain the water;
2. a 3 axis computer controlled scanning mechanism that is mounted on the tank,
3. a field detector mount that moves with the scan mechanism,
4. a reference detector mount that remains stationary during a scan,
5. electrometers with chamber polarization voltage supplies for said mounted detectors,
6. motor controllers for the 3 axis scanning mechanism,
7. a water level sensor that locates the water surface,
8. computer code that controls the detector location and records the detector's dosimetry data,
9. a user interface to the computer that enables
 - a. automatic data collection at pre-programmed field detector locations,
 - b. data processing and analysis that enable data transfer to the TPS system,
10. an optional EDGE detector (diode) for waterproof Field scanning and Reference
11. an optional leveling platform
12. an optional lift table accessory to support the tank

The Sun Nuclear 3D Scanner (Three Dimensional Scanner), Model 1230, is a Radiation Oncology Medical Physics tool used to measure in water the beam characteristics from a delivery machine, such as percent dose curves and beam profiles. The application includes radiotherapy Cobalt 60 and/or LINAC beam acceptance data collection for the treatment planning system (TPS) commissioning of the beam models, as well as periodic or annual measurements of the radiation beams from the delivery machine as described in guidelines such as AAPM TG-142: Quality Assurance of medical accelerators, Med. Phys. 36 (9), Sept 2009, pp.4197 – 4212.

The 3D Scanner electrometer (PC Electrometer Model 1014, 510(k) # K092019) was developed by SNC with functionality that envisioned eventual use in a dosimetry scanner. It incorporates high impedance circuitry that provides the basic means for radiation detection measurement from the same types of detectors that are used in a dosimetry scanner as well as data logging and communication that is essential to the scanner function.

Intended Use:

The 3D Scanner system, model 1230, is intended for radiotherapy dosimetry measurements and export of those measurements for commissioning a treatment planning system (TPS) computer. It is also intended for periodic beam quality assurance (QA) tests as defined by the medical physicist responsible for the QA program.

Similarities and Differences between SNC Model 1230 and IBA RFA-200:

The SNC 3D Scanner Model 1230 conforms to existing technologies that map dose distributions in water.

The technology consists of

1. the ability to move and position encode a water resistant radiation detector in a tank containing water and
2. the ability to measure the response of the detector so as to quantify the relative dose distribution resulting from the transport interaction of the therapeutic radiation beam in water with
3. the ability to record the position and response data in a systematic manner that allows commissioning work flow of the delivery machine that is consistent with the TPS needs

These are the same technologies that are incorporated in the predicate device IBA RFA-200, as well as other models of dosimetry scanners manufactured by IBA (Scanditronix Wellhofer, Schwarzenbruck, Germany), and PTW (Frieburg, Germany).

RFA-200 Intended Use References:

Since the FDA database did not contain the Intended Use of the RFA-200, we offer the following excerpts from IBA literature on the RFA-200:

1. RFA-200 Manual [DAA100 90006 01] Health and safety pg 14
"The person managing the RFA-200 bears the full responsibility for critically evaluating every measurement result and/or manipulating measurements before transferring the data to a treatment planning system."
2. RFA-200 Datasheet:
"The RFA-200 is a two-dimensional radiation field analyzer, designed for commissioning, acceptance, testing and regular QA of linear accelerators. ..."

3. RFA-200 is operated with OmniPro™ –Accept Software, which provides an Intended Use statement in the System Manual [DAA011 90003 07] Overview pg1
“OmniPro Accept is a system software utilizing hardware components to measure radiation dose distribution. The hardware consists of water phantoms, air scanners, film scanner/digitizers, and single or array detectors. The hardware is produced by Scanditronix Wellhofer AB, the sister company Scanditronix Wellhofer GmbH, and by 3rd party vendors.
OmniPro Accept is used to accurately analyze and handle the measured dose distribution for quality assurance purposes, for calibration of radiation devices as input data to treatment Planning Systems, for acceptance testing, beam tuning, and in research.”

Similarities with Marketed Devices:

The SNC 3D Scanner Model 1230 dosimetry Scanner and IBA RFA-200:

1. Both provide a field detector mount that moves with the scan mechanism,
2. Both provide one axis for profile scans on in-plane and cross-plane and keep the detector orientation the same with respect to the beam edge
3. Both provide a reference detector mount that remains stationary during a scan,
4. Both provide a electrometers with chamber polarization voltage supplies for said mounted detectors,
5. Both provide motor controllers for the scanning mechanisms,
6. Both provide computer code that controls the detector location and records the detector's dosimetry data,
7. Both provide a user interface to the computer that enables
 - a. automatic data collection at pre-programmed field detector locations,
 - b. data processing and analysis that enable data transfer to the TPS system,
 - c. basic analysis of beam data tools, e.g. symmetry, flatness, penumbra
 - d. export of beam data to the Treatment Planning System
8. Their intended use is essentially the same. The underlined emphasis in the RFA-200 Intended Use References points out the primary points of agreement.

Differences with Marketed Devices

The SNC 3D Scanner Model 1230 and IBA RFA-200 have the following differences:

1. To contain the water,
 - A. 3D Scanner Model 1230 provides a cylindrical tank {676 mm (D) x 485 mm (H)};
 - B. RFA-200 provides a rectangular tank {638 mm (L) x 440 mm (W) 440 mm (H)}.
2. 3D Scanner Model 1230 provides Ring axis for rotation of the profile scan axis, the RFA-200 requires manual rotation of the profile scan axis (the user rotates the tank),
3. 3D Scanner Model 1230 provides a water level sensor that locates the water surface, the RFA-200 requires manual location by the user sighting the detector/water interface through the acrylic wall
4. 3D Scanner Model 1230 provides profile scan range of 660 mm and depth scan of 400 mm; the RFA-200 provides profile scan range of 495 mm and depth scan of 300 mm.
5. 3D Scanner Model 1230 full weight is 218 kg, RFA-200 full weight is 135 kg



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Noel Downey
Project Materials Manager
Sun Nuclear Corporation
425 Pineda Court
MELBOURNE FL 32940

OCT 1 2010

Re: K101992

Trade/Device Name: 1230-3D Scanner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 1, 2010
Received: July 15, 2010

Dear Mr. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

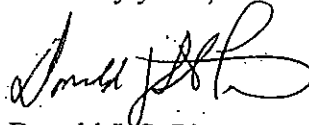
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K101992

Device Name: 1230- 3D Scanner

Indications for Use:

The 3D Scanner system, model 1230, is intended for radiotherapy dosimetry measurements and export of those measurements for commissioning a treatment planning system (TPS) computer. It is also intended for periodic beam quality assurance (QA) tests as defined by the medical physicist responsible for the QA program.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ CIUD

Prescription Use _____

OR

Over-The-Counter Use X

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K101992